

### REMARKS

Applicants wish to thank the Examiner for the review of the present application. Claims 1-21 are currently pending in the application.

#### 35 U.S.C. §102

Claims 1, 2, 6, 7, 9-11, and 13 are rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent 5,247,934 (Wherli et al., hereinafter Wherli).

Claim 1 defines, in relevant part, a method of predicting bone or articular disease that includes determining one or more micro-structural parameters, one or more macroanatomical parameters or biomechanical parameters of a joint. Once the parameters are determined, the method combines at least two of the parameters to predict the risk of bone or articular disease. The two combined parameters include two or more of a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter.

Wherli does not teach such a method. Instead, Wherli discloses a method of diagnosing osteoporosis based solely on trabecular *microstructure* (see col. 3, lines 33-42; col. 4, lines 23-31; col. 9, lines 53-56; col. 10, lines 56-61). Nowhere does Wherlie disclose predicting disease based on two or more of a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter, as required by claim 1. Claim 1 is therefore allowable over Wherlie. In a similar manner, claims 2, 6, 7, 9-11, and 13, which depend from claim 1 and add additional limitations, are allowable over Wherlie for at least the same reasons.

#### 35 U.S.C. §103(a)

Claims 3-5, 8, 12, 20, and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wherli in view of U.S. Patent Number 6,673,298 (Mazess, hereinafter Mazess) in further view of U.S. Patent Number 5,335,260 (Arnold, hereinafter Arnold) in further view of U.S. Patent Number 5,320,102 (Paul et al., hereinafter Paul).

As dependent claims of claim 1, claims 3-5, 8, 12, 20, and 21 include all of the limitations of independent claim 1, which is allowable over Wherli as discussed above.

Therefore, claims 3-5, 8, 12, 20, and 21 are also allowable over Wherlie for the same reasons.

In addition, the disclosures of Mazess, Arnold, and Paul fail to satisfy the deficiencies of Wherli. In particular, none of the additional references disclose a method of predicting disease based on two or more of a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter.

Mazess discloses a method for automatically analyzing the morphometry of bones from data obtained by lateral scans of the bone. Mazess then calculates indicia of bone condition such as length or spacing and compares these indicia to a set of reference values. Nowhere does Mazess disclose extracting trabecular micro-structure from an image. Nor does Mazess disclose determining one or more micro-structural parameters, one or more macroanatomical parameters or biomechanical parameters of a joint, and combining these parameters to predict disease, as required by the claims.

Similarly, Arnold also fails to disclose these features. Instead, Arnold merely discloses a calibration phantom and discusses how to use the calibration phantom to quantify bone mineral density of a patient. Nowhere does Arnold disclose determining one or more micro-structural parameters, one or more macroanatomical parameters or biomechanical parameters of a joint, and combining these parameters to predict disease, as required by the claims.

Paul also fails to disclose the deficiencies of Wherli. Rather, Paul discloses a method for non-invasively diagnosing proteoglycan deficiencies in articular cartilage. The Paul method quantifies a signal intensity of an MRI image and correlates the intensity with a reference signal intensity. Nowhere does Paul disclose extracting trabecular micro-structure from an image. Nor does Paul disclose determining one or more micro-structural parameters, one or more macroanatomical parameters or biomechanical parameters of a joint, and combining these parameters to predict disease, as required by the claims.

Accordingly, as mentioned above, neither Mazess, Arnold or Paul teach the deficiencies of Wherli. Since Wherlie, alone or in combination with Mazess, Arnold and

Paul, fails to teach all required limitation of claims 3-5, 8, 12, 20, and 21, claims 3-5, 8, 12, 20, and 21 are nonobvious and allowable over the cited references.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werli in view of U.S. Patent 5,288,445 (Pak et al., hereinafter Pak). As dependent claims of claim 1, claims 14-19 include all of the limitations of claim 1. As discussed above for claim 1, Werli fails to disclose predicting disease based on two or more of a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter, as required by claims 14-19. Therefore, claims 14-19 are allowable over Werli for at least the same reasons.

In addition, Pak fails to satisfy the deficiencies of Werli. In particular, Pak discloses a treatment process for improving the intrinsic quality of bone in osteoporotic patients by administering a form of sodium fluoride. Pak discusses using spine films to evaluate the treatment (col. 19, lines 31-54), however, Pak does not teach nor suggest predicting disease based on two or more of a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter, as required by claims 14-19 (which depend on claim 1). Further, Pak does not teach nor suggest combining at least two of these parameters to predict the risk of disease. Since Werli, alone or in combination with Pak, fails to teach these required limitation of claims 14-19, claims 14-19 are nonobvious and allowable over the cited references.

It is believed that the application is now in order for allowance and Applicants respectfully request that a notice of allowance be issued. Applicants do not believe that any extension of time is required. However, if any extension of time is required, please charge the associated fees to Deposit Account No. 19-4972. Applicants also request that any other fee required for timely consideration of this application be charged to Deposit Account No. 19-4972.

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Respectfully submitted,

A handwritten signature in dark ink, appearing to read "A. J. Smolenski, Jr.", is written over a horizontal line.

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